EXHIBIT 4

No. _____

United States Court of Appeals for the Third Circuit

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

Appeal from the United States District Court for the District of New Jersey in Case No. 1:19-md-02875 (Honorable Robert B. Kugler)

WHOLESALER DEFENDANTS' PETITION FOR PERMISSION TO APPEAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)

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CORPORATE DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1, Petitioners hereby make the following disclosures:

AmerisourceBergen Corporation has no parent corporation. Walgreens Boots Alliance Inc. is a publicly-held corporation that owns more than 10 percent of AmerisourceBergen Corporation's stock.

Cardinal Health, Inc. is a publicly held corporation that does not have any parent corporations. No publicly held corporation owns 10 percent or more of Cardinal Health, Inc.'s stock.

McKesson Corporation has no parent corporation and no publicly held corporation owns 10 percent or more of McKesson Corporation's stock.

DATED: February 22, 2023

/s/ Clifton S. Elgarten
Clifton S. Elgarten

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INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 23(f), Cardinal Health, Inc., AmerisourceBergen Corporation, and McKesson Corporation ("Wholesalers") respectfully petition this Court for review, and reversal, of the attached class certification order entered February 8, 2023. *See* D.2262 ("Order").[1] Wholesalers join in the arguments advanced contemporaneously by Manufacturer and Pharmacy Defendants, which describe numerous, indefensible legal errors the district court committed in certifying a sprawling, unmanageable class action, including a staggering 111 subclasses. This petition focuses on additional errors specific to Wholesalers, which led to the unprecedented certification of multi-state classes of pharmaceutical product purchasers against the middlemen in the supply chain, based on an inherently individualized unjust enrichment ("UE") claim under the disparate laws of 48 states.[2]

The court certified those classes, and related subclasses, by glossing over or deferring a final decision on multiple issues that it was required to resolve before certification. Resolution of those issues would have confirmed that class certification is improper in this case. Thus, this Court's review is necessary to correct plain error, lest all of the parties be subject to years of burdensome

[1] The Order (D.2262), accompanying Memorandum Opinion (D.2261 "Opinion"), and Appendix (D.2261-5) are submitted as Exhibits A, B, and C, respectively.
[2] For simplicity, "states" as used herein includes D.C. and Puerto Rico.

litigation and pressure to settle in a case that was not suitable for class treatment from the start.

Equally important, Plaintiffs' invocation of a UE theory to try to expand the scope of target class defendants in pharmaceutical cases to include Wholesalers—which have neither fault for nor knowledge of the alleged defect at issue, nor any direct contact with purchasers or consumers—presents a critical issue in connection with pharmaceutical products liability litigation. Due to the individualized determinations inherent in UE claims, and the variation in state laws, courts have universally declined to certify UE claims in similar cases. Given the ruling of the court below, the question of whether or when UE can properly be the foundation for a broad class action like this calls out for this Court's guidance.

In certifying these classes, the court committed at least three critical errors specific to Wholesalers (in addition to those identified by other Defendants), any one of which warrants review.

First, as the Supreme Court has held, if this case is tried, each of the millions[3] of class members—named and unnamed—will have to prove individual standing to sue. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208, 2212 (2021). That requires each Plaintiff to prove, *inter alia*, that their alleged injury is fairly traceable to the acts of "the defendant" that caused that purported harm.

[3] Plaintiffs claim there are "millions of Consumer EL Class Members[.]" D.1748, 3.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). Because of the nature of the pharmaceutical distribution process, establishing a link between a given Wholesaler and a consumer's ingestion of a particular drug is an inherently individualized inquiry, if it is even possible. The court here conceded that it is "not entirely knowable" and may be "*difficult and even impossible* to link which Wholesaler's VCDs were ingested by which consumer," but certified the classes anyway. Opinion 26, 69 (emphasis added). That was clear error, violating the fundamental prerequisites of Rule 23 that individualized issues (like standing) cannot predominate in the trial of a damages class action, and that the class must be readily ascertainable. Fed. R. Civ. P. 23(b)(3); *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 354-55 (3d Cir. 2013) ("As 'an essential prerequisite' to class certification, [a] plaintiff must show by a preponderance of the evidence that the class is ascertainable" based on "objective criteria") (quoting *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012)). Based on the court's own admissions, determining standing for individual class members, if it can be done at all, would require a "considerable, and not entirely knowable, effort[,]" Opinion 26, that necessarily would predominate over any common issues and fail the ascertainability requirement.

Second, the district court hypothesized that it might relieve Plaintiffs of their burden to establish standing on an individual basis by suggesting, without actually

holding, that Wholesalers "may" be subject to "group liability." Opinion 69-70. There is no support for such a theory under state law. And as a matter of federal law, using such a methodology to circumvent standing requirements would violate the Rules Enabling Act, which "forbids interpreting Rule 23 to 'abridge, enlarge or modify any substantive right,' 28 U.S.C. § 2072(b)." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011). Therefore, "a class cannot be certified on the premise that [the defendant] will not be entitled to litigate its … defenses to individual claims." *Id.* And in venturing the "group liability" solution to the intractable difficulty of demonstrating traceability, the district court rested wrongly on the notion that all VCDs at issue in this case were sold by Wholesalers—an assertion that is indisputably false. Further, contrary to this Court's command that a court "cannot take a wait-and-see approach" to "any requirement of Rule 23," *Hayes*, 725 F.3d at 358, the district court reserved for later, ostensibly for the jury, the determination of whether Wholesalers could be subject to "group liability."

Third, Plaintiffs must prove that "questions of law or fact common to class members predominate over any questions affecting only individual members," Fed. R. Civ. P. 23(b)(3). But with respect to the economic loss classes against Wholesalers, highly individualized fact issues inherent in UE claims, as well as numerous variations in UE law among the 48 states at issue, defeat predominance. The district court glossed over those myriad variations, with a superficial attempt

to account for variations by grouping states into subclasses that still fail to overcome the individual legal and factual issues. Moreover, any further re-mapping into more subclasses would create an unmanageable agglomeration of improperly-grouped state subclasses.

The fundamental traceability and standing problems identified above, the use of the novel UE theory—and, indeed, the court's method of deferring, rather than deciding, these crucial issues—go to the heart of class action law and practice, warranting this Court's consideration.

STATEMENT OF THE CASE

Facts. Plaintiffs are consumers and Third-Party Payors ("TPPs") who purchased and/or consumed allegedly contaminated valsartan-containing drugs ("VCDs"). Plaintiffs seek recovery against four different levels of the supply chain: Active Pharmaceutical Ingredient Manufacturers, Finished-Dose Manufacturers, Wholesalers, and Pharmacies.

Wholesalers played an integral but limited role as a simple pass-through entity in the supply chain. Wholesalers did not formulate or manufacture any of the VCDs at issue in this case, nor did they sell or dispense them to consumers or TPPs. Instead, Wholesalers were intermediaries who purchased some, but not all, of the VCDs at issue from Manufacturers, and sold those drugs to Pharmacies, which ultimately dispensed them to unidentified consumers. D.1748, 41-43.

Pharmacies also purchased VCDs directly from Manufacturers and in some cases, from non-defendant wholesalers. *Id.*

Every sale of VCDs since 2015 was accompanied by certain transactional data, called "T3 data," (*e.g.*, D.478-1 ¶¶ 30-34) containing, among other information, the National Drug Code ("NDC") associated with the product. *Id.* When Pharmacies dispensed VCDs to consumers, they maintained a record of the transaction, including the NDC of the VCDs dispensed. *E.g.*, D.2009-14 (Ex. 175).

Plaintiffs contend that the NDC allows them to trace their VCDs back to Wholesalers. D.1748, 58-60. However, the NDC identifies only a product's "labeler, product, and package size and type." 21 C.F.R. § 207.33(a). An NDC does not contain information to identify whether a product was distributed by a given Wholesaler or through any particular distribution channel. *Id.*

The court expressly acknowledged that "there may be a considerable, and not entirely knowable, effort required to link" consumers' VCDs back to Wholesalers, and that "it may be difficult and even impossible to link which Wholesaler's VCDs were ingested by which consumer." Opinion 26, 69.

Plaintiffs' Class Certification Motions. Plaintiffs moved to certify three types of classes against Wholesalers: (1) consumer economic loss; (2) TPP economic loss; and (3) medical-monitoring classes based on Rule 23(b)(2) and

(b)(3). Plaintiffs sought to certify their economic loss classes against Wholesalers based on *one* claim: unjust enrichment.

Decision Below. The court certified nearly all of Plaintiffs' proposed classes against Wholesalers, including the consumer and TPP economic loss classes (six subclasses each), and two medical-monitoring classes. Order 3-4; Opinion 5.

QUESTIONS PRESENTED

1. Whether the district court erred in certifying Wholesaler classes where proof of standing would require literally millions of individualized, case-by-case inquiries to determine whether each class member's purchases can be traced to a specific Wholesaler, which would predominate over any common issues and defeat ascertainability.

2. Whether the district court erred in certifying Wholesaler classes where numerous individual questions of fact and law inherent in Plaintiffs' equitable UE claims predominate over any common issues.

RELIEF SOUGHT

Petitioners seek review and reversal of the February 8, 2023 class certification order, attached as Exhibit A.

STANDARD OF REVIEW

This Court exercises its "very broad discretion" to grant a Rule 23(f) petition "using a more liberal standard" than other circuits. *Laudato v. EQT Corp.*, 23 F.4th 256, 260 (3d Cir. 2022) (internal quotations omitted). Review under Rule 23(f) is

appropriate where "the district court's class certification determination was erroneous" and when, as here, "the appeal might facilitate development of the law on class certification." *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 377 (3d Cir. 2013) (internal quotation and citation omitted); *Laudato*, 23 F.4th at 260.

REASONS WHY THE PETITION SHOULD BE GRANTED

I. CERTIFICATION OF THE WHOLESALER CLASSES WAS ERRONEOUS BECAUSE PLAINTIFFS CANNOT ESTABLISH TRACEABILITY, AND THEREFORE STANDING, WITHOUT MILLIONS OF INDIVIDUAL INQUIRIES THAT DEFEAT PREDOMINANCE AND ASCERTAINABILITY.

The court's decision to certify Plaintiffs' economic loss and medical-monitoring classes against Wholesalers warrants interlocutory review and reversal as the court itself (1) did not determine that traceability is possible, and (2) acknowledged that, even if possible, traceability would be exceedingly complex and individualized for each class member. In short, even if any Plaintiffs *could* trace their VCDs to a specific Wholesaler—a necessary requirement of Article III standing—this could not be done without extensive, individualized factual inquiries that necessarily defeat predominance and ascertainability.

A. Individual Questions Of Proof Are Necessary To Determine Standing For Each Putative Class Member.

In a class action, "[e]very class member must have Article III standing[.]" *TransUnion*, 141 S. Ct. at 2208. "As the party invoking federal jurisdiction," every class member—and here, Plaintiffs say there are millions—must demonstrate standing before they can be awarded relief. *Id.* at 2207, 2212. Furthermore, "in a [class action] that proceeds to trial, the specific facts set forth by the plaintiff to support standing must be supported adequately by the evidence adduced at trial." *Id.* at 2208 (internal quotation and citation omitted).

To establish standing, Plaintiffs must demonstrate not only that they have suffered an actual or imminent particularized "injury in fact," but also that their injury is "fairly traceable" to "the defendant" that caused the injury and redressable by the relief sought. *Lujan*, 504 U.S. at 560. For any class member to have standing to sue a Wholesaler, they must prove that that their specific injury is traceable to a specific Wholesaler. *Id.* After all, a class member could not individually bring a claim for UE against a Wholesaler if they could not demonstrate that their purchase(s) of VCDs "enriched" the specific Wholesaler, whether "unjustly" or not. Rule 23 is not a vehicle for circumventing this fundamental requirement of proof. *Dukes*, 564 U.S. at 367.

B. Individualized Inquiries Will Be Necessary To Establish The Traceability Required For Any Plaintiff To Have Standing, Which Defeats Predominance and Ascertainability.

In opposing class certification, Wholesalers explained how the inability to trace any specific VCD to any specific Wholesaler impacts standing, D.2011, 3-7. The court inexplicably failed to address that issue.[4]

Plaintiffs incorrectly asserted that the NDC contained within specific drug purchase data would allow them to trace their VCDs back to Wholesalers. D.1748, 59-60; *see also* D.1749, 16. The evidence adduced did not support this contention for two reasons.

First, under federal regulations, an NDC identifies only a product's "labeler, product, and package size and type." 21 C.F.R. § 207.33(a); *see also* D.2011, 7-9. It does *not* identify whether a product was distributed by a given Wholesaler or through any particular distribution channel. *Id.*

Second, the uncontradicted evidence before the court established that, even with respect to the named consumer-Plaintiffs, it cannot be reliably determined which Wholesaler, if any, distributed their VCDs.[5] Defendants' records demonstrated that Wholesalers distributed only *some* of the VCDs at issue. D.2011, 7-8, n.12. Some Pharmacies purchased VCDs directly from

[4] The word "standing" appears only once in the Opinion, in the parenthetical of a case cited with respect to a motion to exclude a class expert. Opinion 89.
[5] Here, *named* Plaintiffs have not demonstrated standing, much less the millions of unnamed putative class members.

Manufacturers. Others purchased from non-defendant wholesalers. D.1748, 41-43. Indeed, for the vast majority of named Plaintiffs, the available records provided no information to reliably determine whether their VCDs were distributed with the involvement of a Wholesaler. *Id.*

The court expressly recognized the difficulty, if not impossibility, of proving traceability: "The plaintiffs' enthusiasm for linking all these sets of data notwithstanding," no data set "provide[s] an obvious, tell-tale link between the purchasing consumer and the drug upstream players," and there "may be a considerable, and not entirely knowable, effort required" to identify members of the Wholesaler classes. Opinion 26. The court stated that, at best, "there is a pathway to identify *some* of those Wholesaler to consumer links, *even if imperfectly*," but the court ultimately found that "*it may be difficult and even impossible* to link which Wholesaler's VCDs were ingested by which consumer." *Id.* at 69 (emphasis added).

These conclusions should have led the court to deny certification. The court's statements logically imply that millions of individualized inquires will be necessary to prove standing, but the court did not—and could not—explain how these inquiries would not predominate over any common issues. *See Ferreras v. Am. Airlines, Inc.*, 946 F.3d 178, 184 (3d Cir. 2019) (reversing certification where "the court did not engage with [defendant's] argument that predominance was not

met because individualized proof would be required to" resolve evidentiary issues.). The same is true for Rule 23's ascertainability requirement. If a consumer cannot trace their purchases to a specific Wholesaler, then neither the consumer nor their TPP can be a class member entitled to sue. And "[i]f class members are impossible to identify without extensive and individualized fact-finding or 'mini-trials,' then a class action is inappropriate" *Marcus*, 687 F.3d at 593.

C. The District Court Violated The Rules Enabling Act and Erroneously Took A "Wait-And-See" Approach To Plaintiffs' Failure To Establish Traceability Through Common Evidence.

"[T]he Rules Enabling Act forbids interpreting Rule 23 to 'abridge, enlarge or modify any substantive right,'" and thus "a class cannot be certified on the premise that [the defendant] will not be entitled to litigate its … defenses to individual claims." *Dukes*, 564 U.S. at 367. This Court has held that a trial court "cannot take a wait-and-see approach to … any … requirement of Rule 23." *Hayes*, 725 F.3d at 358. Yet that is exactly what the court did in this case; it certified the subclasses on the premise that Wholesalers will not be "entitled to litigate [their] … defenses" to class member standing on an individual basis. *Dukes*, 564 U.S. at 367. Instead, the court hypothesized a legal theory that would, in its view, punt this seminal issue to the factfinder at the end of the case.

After recognizing the difficulty/impossibility of proving which Wholesaler, if any, distributed a particular VCD, the court appeared to find that this

insurmountable problem would not defeat certification because the "factfinder" at trial *may* find Wholesalers liable on a theory of "group liability" —which the court did not further explain. Opinion 69-70. This holding is doubly wrong. *First*, it relied on the inaccurate premise that Wholesalers distributed every VCD at issue in this case, something even Plaintiffs conceded was not the case. *Second*, it violated the Rules Enabling Act and this Court's admonition that a trial court cannot defer fundamental questions of class certification until trial.

1. There Is No Support For The District Court's Conclusion That All VCDs At Issue Passed Through A Wholesaler Defendant.

To circumvent the traceability issues that defeat standing, predominance, and ascertainability, the court suggested that "even if there is no way to link a specific VCD prescription to an individual Wholesaler, from the larger view, there were no U.S. consumers whose VCDs were distributed by entities other than Wholesaler defendants." Opinion 69. Based on this finding, the court reasoned:

> Even though it may be difficult and even impossible to link which Wholesaler's VCDs were ingested by which consumer, *it is certainly knowable that collectively the Wholesaler defendants here put contaminated VCDs into the U.S. drug supply chain*. It is therefore feasibly ascertainable that medical monitoring damages of putative class members are attributable to the distribution efforts of *all Wholesalers collectively*, for which they may bear group liability. Since such group liability is a determination for a factfinder, the Court does not relieve Wholesalers for liability to this MedMon class. The Court finds the ascertainability requirement met.

Id. at 69-70 (emphasis added).

The court's premise is indisputably false. No party contends that the three Wholesalers exclusively distributed the VCDs at issue. To the contrary, Plaintiffs admit that Pharmacies sometimes purchased VCDs directly from Manufacturers—and in other cases, they purchased from non-defendant wholesalers.[6] Plaintiffs' experts agree. D.2009-7 (Exs. 48, 49, Conti Dep. at 113:8-114:10; Craft Dep. at 204:3-21). Further, Plaintiffs' expert admits that the percentage of VCDs sold through Wholesalers in this case is unknown. *Id.* (Ex. 48, Conti Dep. at 118:19-24).

Accordingly, the court's factual premise for overcoming the fatal predominance and ascertainability problems in this case is incorrect and refuted by evidence from both sides.

2. "Group Liability" Does Not Obviate The Requirements Of Rule 23.

The court's error in holding that Wholesalers were the only entities that sold the VCDs at issue was not harmless. Relying on this fallacy, the court concluded that "group liability" might apply, obviating the need for the extensive individualized inquiries required to trace each Plaintiff's claim to a Wholesaler Defendant, if possible at all. Opinion 69-70. The court did not explain why "group

[6] *See, e.g.*, D.1748, 41 (Pharmacy Walgreens sourced VCDs not only from Wholesalers but also from a non-defendant wholesaler, and directly from Manufacturers); *id*. at 43 (Pharmacy Rite-Aid sourced some of its VCDs directly from Manufacturers).

liability" may be appropriate here, what it meant by "group liability," or how "group liability" overcomes the constitutional requirement to show that each class member has standing. *TransUnion*, 141 S. Ct. at 2212.

If the court was relying on Rule 23 as providing it with the power to impose "group liability," that was manifest error because it violates the Rules Enabling Act. The Federal Rules do not grant the district court the power to change substantive law. *See, e.g.*, *Dukes,* 564 U.S. at 367. That this is a putative class action cannot change that restriction.

Furthermore, the laws of most states governing Plaintiffs' claims do not permit a collective approach to liability—much less allow a party to escape traceability requirements. For example, in *City of Phila. v. Lead Indus. Ass'n, Inc.*, 994 F.2d 112, 114–15 (3d Cir. 1993), the plaintiffs attempted to hold paint manufacturers liable for lead in buildings. Because the plaintiffs were "unable to link a specific manufacturer to the lead pigment in any particular property[,]" they proposed "three theories of collective liability" to establish causation. *Id.* But the Court held that the "plaintiffs may not proceed under these theories because Pennsylvania law has not adopted any of them in products liability cases or sent an authoritative signal that it would do so." *Id*.

Here, the question is even more complicated because Plaintiffs purport to proceed under 48 different states' UE laws. Yet nowhere in its 97-page opinion did

the court provide a single citation to even *one* case from those 48 states holding that the court may dispense with traceability based on a theory of "group liability."

Furthermore, the court did not hold that "group liability" actually applies in this case—only that it "may" apply. Opinion 69-70. The court thus left this important legal determination to the factfinder. But that does not save the certification decision. The court was obliged to "resolve all factual or legal disputes" on which its class certification hinged, and the suggestion that it can simply kick the issue to a jury at some later date is further legal error. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 307 (3d Cir. 2008), *as amended* (Jan. 16, 2009); *Hayes*, 725 F.3d at 358.

II. CERTIFICATION OF THE WHOLESALER UE CLASSES WAS ERRONEOUS BECAUSE INDIVIDUAL ISSUES OF FACT AND LAW PREDOMINATE.

The court's certification of the UE claims against Wholesalers is, quite literally, unprecedented. Neither the court nor Plaintiffs cited a single federal court that has certified a Rule 23 multi-state UE class in an analogous mass tort pharmaceutical case. Courts have universally declined to do so in similar cases. *See, e.g.*, *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2010 WL 2102330, at *8-9, 15-18 (S.D. W. Va. May 25, 2010); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 563 & 573 (E.D. Ark. 2005); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 213-14 (D. Minn. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 69

75 (S.D.N.Y. 2002). The primary reason is that individual issues of law and fact predominate.

When Plaintiffs seek certification under Rule 23(b)(3), they must satisfy the "demanding" requirement of predominance, *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013), by proving that "questions of law or fact common to class members predominate over any questions affecting only individual members," Fed. R. Civ. P. 23(b)(3). "The predominance requirement asks whether the common, aggregation-enabling issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues." *Ferreras*, 946 F.3d at 185 (internal quotations omitted). The predominance analysis must rest on "evidentiary proof," not presumptions. *Comcast*, 569 U.S. at 33-34. Therefore, it is essential that judges conduct a "rigorous analysis of the facts, evidence, and arguments submitted." *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 187 (3d Cir. 2020) (internal quotation omitted).

Individual questions of fact and law predominate in the only cause of action certified against Wholesalers in the economic loss classes—UE.

A. Individual Questions of Fact Predominate.

The equitable nature of UE inherently gives rise to a fact-intensive, individualized inquiry into the totality of the circumstances of each Plaintiff's claim. *See, e.g.*, *Vega v. T-Mobile USA, Inc.,* 564 F.3d 1256, 1274 (11th Cir. 2009)

(because UE claims "turn[ ] on individualized facts[,]" "common questions will rarely, if ever, predominate an unjust enrichment claim"); *Grandalski v. Quest Diagnostics Inc.,* 767 F.3d 175, 185 (3d Cir. 2014) (UE claims require individual inquiries into each class member's alleged injury); *see also Hernandez v. Ashley Furniture Indus., Inc.*, No. 10-5459, 2013 WL 2245894, at *9 (E.D. Pa. May 22, 2013) ("…the unjust enrichment claim essentially *demands* an individualized inquiry… .") (citation omitted) (emphasis in original).

This is especially so in the context of mass tort, pharmaceutical product liability cases where predominance-defeating individual questions often arise, such as whether the "retention of the price paid by class member X would be 'unjust[.]'" *In re Rezulin*, 210 F.R.D. at 69. The unjust enrichment (if any) as to Wholesalers cannot be assessed on a class-wide basis because the value of VCDs to a particular consumer necessarily depends on individualized factors, including the therapeutic benefits to each consumer, the consumer's risk tolerance, the consumer's purchase history, the consumer's actual perceived value of the VCDs, and the NDMA levels in the lot(s) consumed by each class member. *See* D.2011, 23. And, as discussed above, whether any Plaintiff can trace their purchase to a Wholesaler Defendant, thereby conferring standing, is a highly individualized inquiry.

The court failed to adequately assess the individual fact issues that will permeate the certified classes against Wholesalers. In fact, nothing in the court's

opinion addressed the unique status of Wholesalers or the specifics of the UE claim—the sole economic loss claim against Wholesalers. Rather, the court lumped together all of the defendants and claims and brushed aside this predominance concern with two primary errors.

First, while the court acknowledged that the value of the VCDs to a plaintiff will require a "precise calculus[,]" it deferred that issue to the "factfinder." Opinion 37-38, n.27. Thus, rather than perform a rigorous analysis under Rule 23 and address the individualized issue of therapeutic value inherent in Plaintiffs' UE claims—a question that must be answered now to evaluate predominance—the court improperly kicked the can down the road to the jury. That was clear legal error. *In re Hydrogen Peroxide*, 552 F.3d at 307 ("the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits—including disputes touching on elements of the cause of action").

Second, the court erred in concluding that one "singular fact ground[s]" *all* of Plaintiffs' claims against *all* defendants—namely, "defendants' conduct in making contaminated VCDs and in putting these into the U.S. drug supply chain, which plaintiffs paid for." Opinion 21. But the court, failing to address any of the unique Wholesaler issues, ignored the undisputed facts that Wholesalers did not "make" VCDs and had no role in the alleged contamination of the product. D.1748, 5, 49-50 (Plaintiffs' class certification briefing explaining Wholesalers'

role in the supply chain, and averring contamination occurred in the API manufacturing process). Further, the conduct of the defendant is still only one element of *some* states' UE laws. *See generally* D.2011-7; *see also In re McCormick & Co., Inc., Pepper Prod. Mktg. & Sales Pracs. Litig.*, 422 F. Supp. 3d 194, 232 (D.D.C. 2019) (UE requires "a fact-intensive inquiry that focuses on the totality of the circumstances, *not just defendants' conduct*.") (emphasis added).

B. Individual Questions of Law Predominate.

There are also insurmountable differences among the laws of the 48 states at issue that defeat both predominance and manageability.

Predominance: Courts across the country, including within this Circuit, consistently decline to certify UE claims for class action treatment on predominance grounds where the application of multiple states' laws would swamp common issues of law. *See* D.2011, 16-17; D.2011-4; *see also* D.2261-5 (citing 26 cases in 16 courts, including within the Third Circuit, declining to certify UE claims because of variations in state law).

As demonstrated in Wholesalers' briefing below, the multiple differences in how states treat UE include, but are not limited to: (1) whether UE is an independent claim or merely an equitable remedy (D.2011-5); (2) whether a direct relationship or benefit is required (D.2011-6); (3) the standard for the defendants' conduct or level of wrongfulness (D.2011-7); (4) statutes of limitations (D.2011-

8); and (5) available remedies (D.2011-9). And there are multiple permutations even within these categories. For example, of those states that do require a direct benefit to support a UE claim, some also allow for UE claims based on an indirect benefit in limited, varying circumstances. D.2011-6. These differences demonstrate that the elements necessary to establish a class member's UE claim vary between states.

The district court made no attempt to account for these myriad differences in state laws or to explain how any trial could be held on the UE claims without degenerating into a morass of individual issues that would make a trial completely unworkable and impossibly confusing for even the most diligent juror. Nor did the court distinguish the dozens of cases cited by Wholesalers (D.2011, 16-17; D.2011-4) and Manufacturers (D.2008-11) across 16 courts in more than 13 jurisdictions—including in the Third Circuit—that have found UE unsuitable for class certification because of variations in state law.

Instead, the court attempted to "correct" the Plaintiffs' proposed subclasses by purportedly "mapping" them to align with state law variations, reasoning that "correction of plaintiffs' subclasses serves to accurately map the variability of the legal standards for each claim and thus reduce the overall variability of individualized plaintiffs' legal issues." Opinion 22. But the court created these subclasses, Opinion 34-35, based on its analysis of just *one* of the numerous state

law variations (standard for defendant conduct or level of wrongfulness, *see* D.2261-5), while failing to analyze the multiple other categories of key differences between the states' UE laws that Wholesalers raised. *See* D.2011-5, 2011-6, 2011-8, 2011-9, D.2011-10.

If the Court had performed the requisite rigorous analysis—which it did not—it would have found that predominance cannot be met because of the multitude of state law variations. Thus, reversal is required here. *See, e.g.*, *Ferreras*, 946 F.3d at 187 ("Because the District Court did not perform a rigorous analysis, and because … predominance cannot be met under a rigorous analysis, we will reverse the class certification order.").

Manageability: The variations among the 48 applicable state laws also render Plaintiffs' UE classes unmanageable. *See, e.g.*, *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-CV-1833, 2015 WL 3623005, at *35 (E.D. Pa. June 10, 2015) ("variations in state law also render class litigation unmanageable."); *see also Yarger v. ING Bank fsb*, 285 F.R.D. 308, 329 (D. Del. 2012) ("[I]t is unfeasible to have a jury apply sixteen state laws to the unjust enrichment . . . claims, as the elements of each of these claims varies state to state."); *In re Actiq Sales and Marketing Prac. Litig.*, 307 F.R.D. 150, 172 (E.D. Pa. 2015) (acknowledging "the difficulty of managing a class action in which the [unjust

enrichment] laws of TPPs' various home states apply and individual questions of fact predominate.").

Nevertheless, manageability is another issue on which the court simply kicked the can, noting only that its "experience with the MDL" would permit the court to handle the "onerous" and "steep climb" that awaits it in the future. Opinion 24. As discussed above, punting these threshold class certification issues to the jury warrants reversal. *In re Hydrogen Peroxide*, 552 F.3d at 307.

CONCLUSION

In sum, the district court expressed unfounded confidence that it (or a jury) can find legal theories that might make this unprecedented and facially-impossible and unmanageable class action possible and manageable. As shown above, there are no viable legal theories that solve these problems, and this Court's precedent clearly requires these issues to be resolved *before* certifying the class, rather than subjecting the parties to a class action based on the hope that a solution will present itself in the future (or result in a settlement). The traceability difficulties, the novel unjust enrichment theory, and the district court's method of deferring decision on crucial issues, strike at the heart of class action law and practice.

For these reasons, and those in Manufacturers and Pharmacies' petitions, the Court should grant permission to appeal the Order, reverse the Order, and remand

with instructions that Plaintiffs' claims against Wholesalers proceed on an individual basis.

DATED: February 22, 2023

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LOCAL APPELLATE RULE 46.1 CERTIFICATION

I hereby certify, pursuant to L.A.R. 46.1, that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

DATED: February 22, 2023

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CERTIFICATE OF COMPLIANCE, IDENTICAL COPIES AND VIRUS SCAN

I hereby certify that:

1. This petition complies with the type-volume limitation of Fed. R. App. P. 5(c) because it contains 5,200 words, as determined by Microsoft Word, the word processing software used to prepare this petition.

2. This petition also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman size 14 font.

3. The text of the electronic version of the petition filed via CM/ECF is identical to the text of the paper copies filed with the Court.

4. The electronic version of this petition was virus checked using Microsoft Defender version 1.383.358.0, and no virus was detected.

DATED: February 22, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2023, I electronically filed the foregoing Petition for Permission to Appeal under Rule 23(f) with the Clerk of the United States Court of Appeals for the Third Circuit through the CM/ECF system. A true and correct copy was sent via electronic mail per agreement of the underlying parties to the following counsel of record:

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